Informati n Disclosure

Statem nt By Applicant

(Use Several Sheets if Necessary)

Docket: 019/246P

J.S.S.N. 09/244,438

Title: Telomerase Reverse Transcriptase Transcriptional Regulatory

Sequences

Inventors: Morin, G., et al.

Filing Date: 04 Feb 1999

Group: 1642

#### U.S. Patent Documents

| Examine<br>Initial | Ref. | Patent<br>No. | Filing<br>Date                     | Issue<br>Date  | Class/<br>Subclass | Inventors:               | Title:  |
|--------------------|------|---------------|------------------------------------|----------------|--------------------|--------------------------|---|
| JEA                | A    | 5,416,017     | 25 Mar<br>1993                     | 16 May<br>1995 | 435/240.2          | Burton, F.H., et al.     | Cholera Toxin Gene Regulated by Tissue-Specific Promoters                           |
|                    | В    | 5,631,236     | 26 Aug<br>1993                     | 20 May<br>1997 | 514/44             | Woo, S., et al.          | Gene Therapy for Solid Tumors, Using<br>a DNA Sequence Encoding HSV-Tk or<br>VZV-Tk |
|                    | С    | 5,728,379     | 7 Jun 1995                         | 17 Mar<br>1998 | 424/93.2           | Martuza, R., et al.      | Tumor or Cell Specific Herpes Simplex Virus Replication                             |
|                    | D    | 5,998,205     | 1 Jul 1997<br>(pub. 6 Jun<br>1996) | 7 Dec<br>1999  | 435/325            | Hallenbeck, P.L., et al. | Vectors for Tissue-Specific Replication   |
| JEA                | E    | 6,093,809     | 6 May<br>1997                      | 25 Jul<br>2000 | 536/23.5           | Cech, T., et al.         | Telomerase  |

Foreign Patent or Published Foreign Patent Application

|    | aminer | Ref. | Document    | Publ.          | Juris-  | Title:   | Translati    |    |
|----|--------|------|-------------|----------------|---------|--|--------------|----|
| t  | nitial | 1 10 | No.         | Date           | diction | 1140.  | Yes          | No |
| JE | A      | F    | WO 98/07838 | 26 Feb<br>1998 | PCT     | Higher Animal Telomerase Protein and Gene Encoding the Same  | X<br>summary | ×  |
|    |        | G    | WO 98/14592 | 9 Apr 1998     | PCT     | Telomerase Reverse Transcriptase   |              |    |
|    |        | Н    | WO 98/14593 | 9 Apr 1998     | PCT     | Human Telomerase Catalytic Subunit   |              |    |
|    |        | 1    | WO 98/21343 | 22 May<br>1998 | PCT     | Genes Encoding Telomerase Proteins   |              |    |
|    |        | J    | WO 98/37181 | 27 Aug<br>1998 | PCT     | Telomerase Catalytic Subunit Gene and Encoded Protein  |              |    |
|    |        | к    | WO 99/01560 | 1 Jan 1999     | PCT     | Vertebrate Telomerase Genes and Proteins and Uses<br>Thereof   |              |    |
| \  |        | L    | WO 99/33998 | 8 Jul 1999     | PCT     | Regulatory DNA Sequences of the Human Catalytic<br>Telomerase Sub-Unit Gene, Diagnostic and Therapeutic<br>Use Thereof | X<br>partial | x  |
| J  | EA     | М    | WO 99/38964 | 5 Aug 1999     | PCT     | Promoter Regions of the Mouse and Human Telomerase<br>RNA Component Genes  |              |    |

| Examiner | Date Considered |
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Inventors: Morin, G., et al.

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## Other Documents

| Examiner<br>Initial | Ref.  | Author, Title, Date, Source  |  |  |  |  |  |  |  |
|---------------------|---|--|--|--|--|--|--|--|--|
| JEA                 | N   | Berenstein, M., et al., "Different efficacy of <i>in vivo</i> herpes simplex virus thymidine kinase gene transduction and ganciclovir treatment on the inhibition of tumor growth of murine and human melanoma cells and rat glioblastoma cells", <i>Cancer Gene Therapy</i> , 6(4):358-366 (1999) |  |  |  |  |  |  |  |
|                     | 0   | Bi, W., et al., "An HSVtk-mediated local and distant antitumor bystander effect in tumors of head and neck origin in athymic mice", Cancer Gene Therapy, 4(4):246-252 (1997)   |  |  |  |  |  |  |  |
|                     | Р   | and, K., et al., "Tumor cell-specific transgene expression prevents liver toxicity of the adeno-HSVtk/GCV approach",<br>the Therapy, 5:1363-1371 (1998)  |  |  |  |  |  |  |  |
|                     | a   | ong, YS., et al., "The Human Telomerase Catalytic Subunit hTERT: Organization of the Gene and Characterization of the omoter", Human Molecular Genetics, 8(1):137-142 (1999)   |  |  |  |  |  |  |  |
|                     | R   | evereux, T.R., et al., " DNA Methylation Analysis of the Promoter Region of the Human Telomerase Reverse ranscriptase (hTERT) Gene", Cancer Res., 59:6087-6090 (15 Dec 1999)   |  |  |  |  |  |  |  |
|                     | s   | Eshami, A.A., et al., "The effect of promoter strength in adenoviral vectors containing herpes simplex virus thymidine inase on cancer gene therapy in vitro and in vivo", Cancer Gene Therapy, 4(4):213-221 (1997)  |  |  |  |  |  |  |  |
|                     | · T   | Horikawa, I., et al., "Cloning and Characterization of the Promoter Region of Human Telomerase Reverse Transcriptations", Cancer Res., 59:826-830 (15 Feb 1999)  |  |  |  |  |  |  |  |
|                     | υ   | Klatzmann, D., et al., "A Phase VII Dose-Escalation Study of Herpes Simplex Virus Type I Thymidine Kinase "Suicionane", Human Gene Therapy, 9:2585-2594 (20 Nov 1998)  |  |  |  |  |  |  |  |
|                     | V Klatzmann, D., et al., "A Phase VII Study of Herpes Simplex Virus Type I Thymidine Kinase "Suicide" Gene Tr<br>Recurrent Glioblastoma", <i>Human Gene Therapy</i> , 9:2595-2604 (20 Nov 1998) |  |  |  |  |  |  |  |  |
|                     | w   | Li, PX., et al., "Differential chemosensitivity of breast cancer cells to ganciclovir treatment following adenovirus-mediated herpes simplex virus thymidine kinase gene transfer", Cancer Gene Therapy, 6(2):179-190 (1999)   |  |  |  |  |  |  |  |
|                     | ×   | Princen, F., et al., "Repeated cycles of retrovirus-mediated HSVtk gene transfer plus ganciclovir increase survivith peritoneal carcinomatosis", Gene Therapy, 5:1054-1060 (1998)  |  |  |  |  |  |  |  |
|                     | Υ   | Robertson, M.W., III, et al., "Use of a tissue-specific promoter for targeted expression of the herpes simplex virus thymidine kinase gene in cervical carcinoma cells", Cancer Gene Therapy, 5(5):331-336 (1998)  |  |  |  |  |  |  |  |
|                     | Z   | Shand, N., et al., "A Phase 1-2 Clinical Trial of Gene Therapy for Recurrent Glioblastoma Multiforme by Turnor Transduction with the Herpes Simplex Thymidine Kinase Gene Followed by Ganciclovir", <i>Human Gene Therapy</i> , 10:2325-2335 (20 Sep 1999)   |  |  |  |  |  |  |  |
|                     | AA  | Siders, W.M., et al., "Melanoma-specific cytotoxicity induced by a tyrosinase promoter-enhancer/herpes simplex virus thymidine kinase adenovirus", Cancer Gene Therapy, 5(5):281-291 (1998)  |  |  |  |  |  |  |  |
|                     | AB  | Smiley, W.R., et al., "Establishment of Parameters for Optimal Transduction Efficiency and Antitumor Effects with Purified High-Titer HSV-TK Retroviral Vector in Established Solid Tumors", Human Gene Therapy, 8:965-977 (20 May 1997)   |  |  |  |  |  |  |  |
|                     | AC  | Sterman, D.H., et al., "Adenovirus-Mediated Herpes Simplex Virus Thyrnidine Kinase/Ganciclovir Gene Therapy in Patients with Localized Malignancy: Results of a Phase I Clinical Trial in Malignant Mesothelioma", <i>Human Gene Therapy</i> , 9:1083-1092 (1 May 1998)                            |  |  |  |  |  |  |  |
|                     | AD  | Su, H., et al., "Tissue-specific expression of herpes simplex virus thymidine kinase gene delivered by adeno-associated virus inhibits the growth of human hepatocellular carcinoma in athymic mice", <i>Proc. Natl. Acad. Sci. USA</i> , 94:13891-13896 (Dec 1997)                                |  |  |  |  |  |  |  |
|                     | AE  | Takakura, M., et al., "Cloning of Human Telomerase Catalytic Subunit (hTERT) Gene Promoter and Identification of Proximal Core Promoter Sequences Essential for Transcriptional Activation in Immortalized and Cancer Cells", Cancer Res., 59:551-557 (1 Feb 1999)                                 |  |  |  |  |  |  |  |
|                     | AF  | Wick, M., et al., "Genomic organization and promoter characterization of the gene encoding the human telomerase reverse transcriptase (hTERT)", Gene, 232:97-106 (1999)  |  |  |  |  |  |  |  |
|                     | AG  | Wildner, O., et al., "Adenoviral vectors capable of replication improve the efficacy of HSVtt/GCV suicide gene therapy of cancer", Gene Therapy, 6:57-62 (1999)  |  |  |  |  |  |  |  |
| $\sqrt{}$           | АН  | Wildner, O., et al., "Therapy of Colon Cancer with Oncolytic Adenovirus Is Enhanced by the Addition of Herpes Simplex Virus-thymidine kinase", Cancer Research, 59:410/413 (1999)  |  |  |  |  |  |  |  |
| JEA                 | Al  | Wu, KJ., et al., *Direct activation of TERT transcription by c-MYC*, Nature Genetics, 21:220-224 (Feb 1999)  |  |  |  |  |  |  |  |

| Examiner | Date Considered |
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Information Disclosure

Stat m nt By Applicant

(Use S veral Sheets if Necessary)

Docket: 019/246P

3.S.S.N. 09/244,438

Title: Telomerase Reverse Transcriptase Transcriptional Regulatory

Sequences

Inventors: Morin, G., et al.

Filing Date: 04 Feb 1999

Group: 1642

| Examiner<br>Initial | Ref. | Author, Title, Date, Source  |
|---------------------|------|--|
| JEA                 | AJ   | Yang, L., et al., "Intercellular Communication Mediates the Bystander Effect During Herpes Simplex Thymldine<br>Kinase/Ganciclovir-Based Gene Therapy of Human Gastrointestinal Tumor Cells", <i>Human Gene Therapy</i> , 9:719-728 (20<br>Mar 1998) |
| JEA                 | AK   | U.S. Patent Application Serial No. 08/974,549, "Human Telomerase Catalytic Subunit", filed 19 Nov 1997   |

| Examiner | Date Considered |
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Docket: 019/246P Supplemental

\$S.S.N. 09/244,438

Inf rmation Disclosur

Title: Telomerase Reverse Transcriptase Transcriptional Regulatory

Sequences

Stat m nt By Applicant

Inventors: Morin, G., et al.

(Use Several Sheets if Necessary)

Filing Date: 04 Feb 1999

Group: 1642

|          | Foreign Patent or Published Foreign Patent Application |            |        |         |   |       |         |  |  |
|----------|--|------------|--------|---------|---|-------|---------|--|--|
| Examiner | Ref.   | Document   | Publ.  | Juris-  | Title:  | Trans | slation |  |  |
| Initial  | 1.0  | No.        | Date   | diction | Tiue.   | Yes   | No      |  |  |
| AV       | Α  | GB 2317891 | 4/8/98 | UK      | hTRT, the reverse transcriptase subunit of human telomerase |       |         |  |  |
| 7 /      | -  |            |        |         |   |       |         |  |  |

| Examiner | Date Considered |
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Information Disclosur

Statem nt By Applicant

(Use Several Sheets if Necessary)

Docket: 019/246P Suppl.

ನ.S.N. 09/244.438

Title: TELOMERASE PROMOTER DRIVING EXPRESSION OF THERAPEUTIC

GENE SEQUENCES Inventors: Morin, et al.

Filing Date: 04 February 1999

Group: 1635

**U.S. Patent Documents** 

| Exam<br>Initi |                   | Ref.    | Patent<br>No. | Filing<br>Date | tssue<br>Date | Class/<br>Subclass | Inventors:            | Title:   |
|---------------|-------------------|---------|---------------|----------------|---------------|--------------------|-----------------------|--|
| M             | $\mathcal{U}_{l}$ | ВА      | 5,907,083     | Mar 18/96      | May 25/99     | 800/205            | Robert et al.         | Brassica Sp. Gene Promoter Highly<br>Expressed During Stigma<br>Development  |
| $\square$     |                   | 88      | 6,054,575     | Dec 24/97      | Apr 25/00     | 536/24.31          | Villeponteau et al.   | Mammalian Telomerase RNA Gene<br>Promoter  |
|               |                   | ВС      | 6,228,643     | Mar 22/97      | May 8/01      | 435/419            | Greenland et al.      | Promoter   |
|               |                   | BD      | 6,274,790     | Apr 10/98      | Aug 14/01     | 800/287            | Kunst et al.          | Nucleic Acids Encoding a Plant<br>Enzyme Involved in Very Long Chain<br>Fatty Acid Synthesis   |
|               |                   | BE      | 6,281,409     | Nov 4/96       | Aug 28/01     | 800/287            | Woodhead et al.       | Blackcurrent Promoters and Genes   |
|               |                   | BF<br>/ | 6,300,095     | Mar 5/98       | Oct 9/01      | 435/69.1           | Barredo Fuente et al. | Promoters of the Genes Glutamate<br>Dehydrogenase β-N-<br>Acetylhexosaminidase and y-Actin<br>and Their Use in Filamentous Fungi<br>Expression, Secretion and Antisense<br>Systems |
|               |                   | BG      | 6,306,656     | Oct 13/99      | Oct 23/01     | 435/419            | Liu et al.            | Plant Embryo-and Aleurone-Specific Promoter  |
|               |                   | вң      | 6,331,527     | Nov 1/99       | Dec 18/01     | 514/44             | Parmacek et al.       | Promoter Smooth Muscle Cell<br>Expression  |

Foreign Patent or Published Foreign Patent Application

| Examiner Initial | Ref. | Document<br>No. | Publ.<br>Date | Juris-<br>diction | Title: | Translation |  |
|------------------|------|-----------------|---------------|-------------------|--------|-------------|--|
|                  | None |                 |               |                   |        |             |  |

Other Documents

| Examiner<br>Initial | Ref. | • | Author, Title, Date, Source |
|---------------------|------|---|-----------------------------|
|                     |      |   | None                        |

| Examiner Date Considered |  |
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Examiner: Initial if citation considered, whether or not citation is in conformance with MPEP 609; draw line through citation if not in conformance and not considered. Include copy of this form with next communication to applicant.

PTO-1449 — Page 1

| F rm 1449 (modified)                             | Docket: 019/246   | S.N. 09/244,438   |  |  |  |
|--|---|---|--|--|--|
| inf rmati n Discl sure<br>Statement By Applicant | Title: Telomerase Promoter Drivin Inventors: Gregg Morin et al. | Title: Telomerase Promoter Driving Expression of Therapeutic Gene Sequences Inventors: Gregg Morin et al. |  |  |  |
| (Use Several Sheets if Necessary)                | Filing Date: February 4, 1999                                   | Group: 1635   |  |  |  |

## **U.S. Patent Documents**

| Examiner<br>Initial | Ref. | Patent<br>No. | Filing<br>Date | Issue<br>Date | Class/<br>Subclass | Inventors: | Title: |
|---------------------|------|---------------|----------------|---------------|--------------------|------------|--------|
| (none)              |      |               |                |               |                    |            |        |

# Foreign Patent or Published Foreign Patent Application

| Examiner | Ref. | Document    | Publ.     | Juris-  | Title:   | Translation |    |
|----------|------|-------------|-----------|---------|--|-------------|----|
| Initial  | nei. | No.         | Date      | diction | Title.   | Yes         | No |
|          | CA   | WO 00/46355 | Aug 10/00 | PCT     | Telomerase ReverseTranscriptase Transcriptional Regulatory Sequences |             |    |
|          |      |             |           |         |  |             |    |

## Other Documents

|   | Exami<br>Initia |                | Ref. | Author, Title, Date, Source  |
|---|-----------------|----------------|------|--|
|   | X               | $\overline{)}$ | СВ   | Majumdar et al. The telomerase reverse transcriptase promoter drives efficacious tumor suicide gene therapy while preventing hepatotoxicity encountered with constitutive promoters. Gene Therapy 8:568, 2001.                         |
|   | U               | T              | СС   | Koga et al. A novel telomerase-specific gene therapy: Gene transfer of caspase-8 utilizing the human telomerase catalytic subunit gene promoter. Hu. Gene Ther. 11:1397, 2000.   |
| Ī | (               |                | CD   | Gu et al. Tumor-specific transgene expression from the human telomerase reverse transcriptase promoter enables targeting of the therapeutic effects of the Bax gene to cancers. Cancer Res. 60:5339, 2000.                             |
|   |                 |                | CE   | Komata et al. Treatment of malignant glioma cells with the transfer of constitutively active Caspase-6 using the human telomerase catalytic subunit (human telomerase reverse transcriptase) gene promoter. Cancer Res. 61:5796, 2001. |
|   | W               |                | CF   | Geron Corporation Press Release Geron Corporation and Genetic tTherapy, Inc. partner to develop cancer therapy. January 7, 2002.   |
|   | <del></del>     |                | ,    |  |

| Examiner   | Date Considered | 9-16-06 |
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PTO-1449 — Page 1

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Statement By Applicant

(Use Several Sheets if Necessary)

Docket: 019/246P

S.S.N. 09/244,438

Telomerase Reverse Transcriptase Transcriptional Regulatory

Sequences Morin, G., et al.

Filing Date: 04 Feb 1999

Group: 1632

**U.S. Patent Documents** 

| Examiner<br>Initial | Ref. | Patent<br>No. | Filing<br>Date | Issue<br>Date | Class/<br>Subclass | Inventors: | Title: |
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| (NONE)              |      |               |                |               |                    |            |        |

Foreign Patent or Published Foreign Patent Application

| Examiner<br>Ipitial | Ref. | Document / No. | Publ.<br>Date | Juris-<br>diction | Title:  | Translation |
|---------------------|------|----------------|---------------|-------------------|---|-------------|
|                     | X    | WO 99/33998    | 8 Jul 1999    | PCT               | Regulatory DNA Sequences of the Human Catalytic<br>Telomerase Sub-Unit Gene, Diagnostic and<br>Therapeutic Use Thereof                        | Abstract    |
| 8/                  | ıs   | WO 99/33998    | 8 Jul 1999    | PCT               | PARTIAL ENGLISH TRANSLATION: Regulatory DNA Sequences of the Human Catalytic Telomerase Sub-Unit Gene, Diagnostic and Therapeutic Use Thereof | Partial     |

## Other Documents

| Examiner<br>Initial | Ref. | Author, Title, Date, Source |  |  |  |  |  |
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PTO-1449 — Page 1

| F rm 1449 (modified)                            | Docket: 019/246   | U.S.S.N. 09/244,438                  |
|---|---|--------------------------------------|
| inf rmati n Discl sur<br>Statement By Applicant | Title: Telomerase Promoter Driving Expr<br>Gene Sequences<br>Inventors: Gregg B. Morin et al. | Group: 1635                          |
|   | Filing Date: February 4, 199  | Examiner: Richard A. Schnizer, Ph.D. |

#### **U.S. Patent Documents**

| Examiner<br>Initial | Ref. | Patent<br>No. | Filing<br>Date | Publish<br>Date | Class/<br>Subclass                  | Inventors:   | Title:   |
|---------------------|------|---------------|----------------|-----------------|-------------------------------------|--------------|--|
| JEA                 | DA   | 6,610,839     | Sep 29/99      | Aug 26/03       | 536/024.1;<br>435/194;<br>435/320.1 | Morin et al. | Promoter for telomerase reverse transcriptase (cover & claims) |
| JEA                 | DB   | 6,610,839     | Sep 29/99      | Aug 26/03       | 536/024.1;<br>435/194;<br>435/320.1 | Morin et al. | Promoter for telomerase reverse transcriptase (specification)  |
|                     |      |               |                |                 |                                     |              |  |

# Foreign Patents and Published Foreign Patent Applications

| Examiner<br>Initial | Ref. | Document<br>No. | Publish<br>Date | Juris-<br>diction | Title: | Trans-<br>lation |
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| (None)              |      |                 |                 |                   |        |                  |

# Other Documents

| Examiner<br>Initial | Ref. | Author, Title, Date, Source |  |
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|                     |      | (None)                      |  |

| Examiner /Jon Eric Angell/ | Date Considered 09/18/2006 |
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